

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT:	BROWN, et al.	)	EXAMINER: KINSEY WHITE, N.
SERIAL NO.:	10/579,606	)	
FILED:	May 16, 2006	)	ART UNIT: 1648
FOR:	Mutant Viruses	)	CONFIRM. NO.: 9388

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION REGARDING AVAILABILITY OF HSV1716/CMV-NTR/GFP TO  
THE PUBLIC**

Sir:

I, ROBERT SPAVIN, declare that I am empowered to act on behalf of Assignee Crusade Laboratories Limited, who is the Assignee of the above-identified application in entirety (Reel 017898 Frames 0169 and 0173) and do hereby declare as follows:

1. Claim 57 of the above-captioned patent application has been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement in the Office Action dated October 31, 2007. The Examiner states that although on page 6 the HSV strain has been deposited, there is no indication of public availability. The Examiner states that the deposit requirement would be satisfied upon filing of a statement, affidavit or declaration by Applicants or someone empowered to make such a statement that the instant invention will be irrevocably and without restriction released to the public upon issuance of the patent.

2. The specification at page 6 states that "HSV1716/CMV-NTR/GFP has been deposited in the name of Crusade Laboratories Limited having an address at Department of Neurology Southern General Hospital 1345 Govan Road Govan Glasgow G51 5TF Scotland on 5 Nov. 2003 at the European Collection of Cell Cultures (ECACC), Health Protection Agency, Porton Down, Salisbury, Wiltshire, SP4 0JG, United Kingdom under accession number 03110501 in accordance with the provisions of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (herein referred to as the 'Budapest Treaty')."

3. I declare that the deposit referenced in Paragraph 2 above was made under conditions that assure access to the deposit in accordance with the provisions of 37 CFR § 1.808. Specifically, I declare that the instant invention will irrevocably and without restriction be released to the public upon the issuance of the patent, potentially subject only to the conditions of 37 CFR § 1.808(b) as permitted by 37 CFR § 1.808(a).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 31<sup>st</sup> January 2008

By: Zolt E. Spavin

LEGAL COUNSEL

CRUSADE LABORATORIES LTD

THE COMPLETE CELL SOLUTION



# Centre for Applied Microbiology and Research and European Collection of Cell Cultures

This document certifies that  
Virus                    HSV1716/CMV-NTR/GFP  
Deposit Reference 03110501

has been accepted as a patent deposit, in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on  
05 November 2003

.....  
Dr D H Lewis  
General Manager  
ECACC

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

TO  
DR PAUL DUNN  
CRUSADE LABORATORIES LTD  
DEPARTMENT OF NEUROLOGY  
SOUTHERN GENERAL HOSPITAL  
1345 GOVAN ROAD  
GOVAN, GLASGOW  
G51 5TF  
SCOTLAND

NAME AND ADDRESS  
OF DEPOSITOR

INTERNATIONAL FORM

## I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the  
DEPOSITOR:

HSV1716/CMV-NTR/GFP

Accession number given by the  
INTERNATIONAL DEPOSITORY AUTHORITY:

03110501

## II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

☒ A scientific description☐ A proposed taxonomic designation

(Mark with a cross where applicable)

## III. RECEIPT AND ACCEPTANCE

This International Depository Authority accepts the microorganism identified under I above,  
which was received by it on 05 November 2003 (date of the original deposit)<sup>1</sup>

## IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International  
Depository Authority on (date of the original deposit) and  
A request to convert the original deposit to a deposit under the Budapest Treaty  
is received by it on (date of receipt of request for conversion)

## IV. INTERNATIONAL DEPOSITORY AUTHORITY

Name: Dr D H Lewis

Address: ECACC  
CAMR  
Porton Down  
Salisbury SP4 0JG

Signature(s) of person(s) having the power  
to represent the International Depository  
Authority or of authorized official(s):

Date: 8/12/03

<sup>1</sup> Where Rule 6.4(d) applies, such date is the date on which the status of international depository  
authority was acquired

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

TO  
DR PAUL DUNN  
CRUSADE LABORATORIES LTD  
DEPARTMENT OF NEUROLOGY  
SOUTHERN GENERAL HOSPITAL  
1345 GOVAN ROAD  
GOVAN, GLASGOW  
G51 5TF  
SCOTLAND

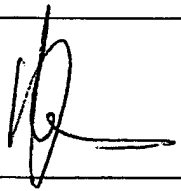
VIABILITY STATEMENT  
Issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified on the following page

NAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY OF STATEMENT  
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
<p>me: DR PAUL DUNN CRUSADE LABORATORIES LTD DEPARTMENT OF NEUROLOGY SOUTHERN GENERAL HOSPITAL</p> <p>Address: 1345 GOVAN ROAD GOVAN, GLASGOW G51 5TF SCOTLAND</p>	<p>Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:  03110501</p> <p>Date of the deposit or of the transfer:  05 November 2003</p>
<p>II. VIABILITY STATEMENT</p> <p>The viability of the microorganism identified under II above was tested on 05 November 2003<sup>2</sup>. On that date, the said microorganism was</p> <p><input checked="checked" type="checkbox"/> , viable</p> <p><input type="checkbox"/> , no longer viable</p>	

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

Form BP/4 (first page)

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED <sup>4</sup>	
The Virus Patent Deposit HSV1716/CMV-NTR/GFP Accession Number 03110501 was tested according to the Depositor's protocol and shown to be Infectious and Viable.	
II. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: Dr D H Lewis ECACC CAMR Address: Porton Down Salisbury Wiltshire SP4 0JG	 Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): Date: 8/12/03

4 Fill in if the information has been requested and if the results of the test were negative.

Form BP/9 (second and last page)